Médecins du Monde Challenges Pfizer/BioNTech Monopoly on the Covid-19 Vaccine

Third party observations of Comirnaty® patents EP3901260 and EP3901261
Vaccines are considered essential tools in the fight against the Covid-19 pandemic, yet only a few pharmaceutical companies have control over the production and sale of these technologies; they are generating vast profits while leaving 2.6 billion people without access to them. Médecins du Monde is challenging this monopoly by taking legal action at the European Patent Office (EPO).

**A clear lack of inventive step, which is part of the required criteria for obtaining a patent**

Médecins du Monde believes the two patent applications filed by BioNTech at the EPO are undeserved. BioNTech has directly implemented existing knowledge from the development of vaccines for other coronaviruses and mRNA vaccines, both of which were produced by academic researchers. In other words, Pfizer/BioNTech needed only a few weeks to produce its Covid-19 vaccine, because the science was already there.

**Unlimited profits for a few private companies at the detriment of public interest**

The public sector has provided more than $50 billion to private companies to support research and development (R & D) for Covid-19 vaccines, while assuming the financial risk of their development. Today, Pfizer/BioNTech holds 70% of the European Covid-19 vaccine market. They generated tens of billions of dollars in 2021, while forecasts promise record-breaking global sales in 2022.

It is time for European states, and France in particular, to regain control and allow more equitable sharing of public investments. In France, more than €4 billion could have been saved and redirected to the public health system in 2021 and 2022. The government can still intervene and rebalance its resources between a few private companies and the general interest.

[Image of a campaign poster with text: HEALTH. WHO SHOULD LAY DOWN THE LAW, THE MARKET OR THE STATE? Sign the petition to help reduce the cost of medicines at www.thecostoflife.co.uk]

https://leprixdelavie.medecinsdumonde.org/fr-FR/
Our recent experiences with the Covid-19 pandemic show strong paradoxes.

**Paradox 1:** Vaccines are considered to be essential in the fight against the Covid-19 pandemic. Although governments declared a global-scale war against Covid-19, claiming that anti-Covid technologies should be for “common good”, they agreed to grant monopoly rights on these essential tools through patents and other intellectual property (IP) rights (see Box 2). As a consequence, a few companies are in a position of control over the production and trade of these technologies, and millions of people in the world are excluded from access to them (see Figure 1).

**Paradox 2:** Governments have invested billions of taxpayer euros in health, but the “whatever it takes” policy that governments use with multinational pharmaceutical companies has had a significant, unanticipated cost to health itself. Indeed, while a few pharmaceutical companies make billions of euros in profit (see Figure 2), there are massive shortages of resources for the healthcare system (see Figure 8). Often, the public pays twice for the research and development (R & D) of pharmaceutical products, once for R & D, and again for high-priced patented products (see Figure 3). This double-billing - for development and sales of a product - allows a handful of multinational pharmaceutical companies to generate vast profits.

These paradoxes illustrate the imbalances in policies for health and pharmaceuticals that the French government has implemented and continues to support.

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**Figure 1. Flagrant Worldwide Disparity in Access to Covid-19 Vaccines**

<table>
<thead>
<tr>
<th>HIGH INCOME COUNTRIES</th>
<th>LOW INCOME COUNTRIES</th>
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<tbody>
<tr>
<td>44% of the population received a booster dose</td>
<td>only 0.38% of the population received a booster dose</td>
</tr>
<tr>
<td>~75% COMPLETE PRIMARY VACCINATION</td>
<td>~11% COMPLETE PRIMARY VACCINATION</td>
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**Box 1. Creation of patent pool during WW1 to foster production of airplanes**

When the United States (US) government needed more airplanes during World War I, it formed a patent pool to speed up their development and deployment, and got all patent holders to join it. The US congress passed the Naval Appropriation Act of the Fiscal Year 1918, which budgeted for the purchase or “condemnation” of airplane patents. The Manufacturers Airplane Association (MAA) was formed: every major producer of airplanes was a member of the Association, paying royalties to it to use patents held by others.

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Box 2: What is a patent – What is the impact of patents on production and prices?

A patent is a legal title, granted by a state for its territory to ensure a monopoly (for a period at least 20 years, according to the World Trade Organization’s [WTO] rules) on production, sale, import and export of an invention. The initial design of patents was intended to ensure a fair balance between the private interests of the inventor and general public interest.

But the proliferation of pharmaceutical patents has caused serious abuses and negative side-effects. These monopolies, which prevent any form of competition, enable pharmaceutical companies to demand and succeed in obtaining high prices for medicines: indeed, as the only legal source for a product, the patent owner controls production and enjoys a strong bargaining position. Only a company authorized (through a license) by the patent owner can manufacture the product and supply it (except if the State takes special measures and issues a compulsory license (CL) to authorize third parties to do so - which France refuses to do even in legitimate cases (see Box 6)).

France, and 34 other countries, are members of the European Patent Convention. In these countries, patents can be granted by the European Patent Office (EPO) or by national patent offices; 95% of all patents are granted by the EPO.

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Médecins du Monde (Doctors of the World; MDM) believes that the EPO should not grant two patents related to the Pfizer/BioNTech Covid-19 vaccine, EP3901260 and EP3901261, which were filed by BioNTech. MDM has submitted third-party observations (see Box 3) to the EPO on these two patent applications. One of the applications stresses the association between mRNA and a lipid nanoparticle (LNP, which are tiny balls that deliver mRNA into cells); the other relates to mRNA sequences and the SARS-CoV-2 spike protein it encodes.

According to the European Patent Convention, a patent must satisfy three patentability criteria to be granted:

- Novelty: an invention is considered new if it is not already known.
- Inventive step: the invention must not obviously derive from the prior art (prior art is any evidence that your invention is already known).
- The invention must be considered “susceptible to industrial application”; it must be suitable for use or manufacture in any industry.

In these two cases, the patent applications show a clear lack of inventive step. BioNTech, has directly implemented existing knowledge from development of vaccines for other coronavirus, and from development of mRNA vaccines, which was produced by academic researchers. BioNTech applied this knowledge to a new virus, SARS-CoV-2, knowing that its genetic sequence had already been identified by academic researchers (see Figure 4).

It is as if you claimed to have invented an apple cutter, while you merely used a previously existing apple cutter to a new type of apple that someone else discovered.

The subject-matter of patent application EP301260 lacks an inventive step, because the association of mRNA and a LNP was previously characterized in a scientific article describing an HIV mRNA-based vaccine, and because Chinese researchers identified and published the genetic sequence of SARS-CoV-2 in 2020, before BioNTech began to develop its mRNA-based Covid-19 vaccine.

Regarding application EP3901261, a published article in 2019 describes development of vaccines against other coronaviruses, by stabilizing the spike protein with an antigenically optimal conformation, thanks to the introduction of 2 amino acid prolines (2P). BioNTech is trying to use its introduction of 2P into the SARS-CoV-2 spike protein to argue that they have made an innovative vaccine.

EP3901260 and EP3901261 were filed in April 2020, three months after the sequence of SARS-CoV-2 was published – reflecting the time it took to write a patent applying an existing technology to a new virus. After that, the companies had to test the technology, first in animals, then in people, which was done very quickly (given the urgency in addressing the pandemic). It is clear how and why BioNTech (and other pharmaceutical companies) were able to develop a Covid-19 vaccine in a very limited amount of time: all the science was already there.
**Figure 3. The Science was Already There**

**2005**  
Using pseudouridine (Ψ) to produce therapeutic mRNA, University of Pennsylvania

...CGAGΨCGΨΨAA...

**2009**  
Defining the composition of lipid nanoparticle (LNP) for administering mRNA, University of Pennsylvania

**2017**  
First description of stabilizing coronavirus spike protein with the introduction of two amino acid prolines; joint academic work

**2019**  
Implementation of an association between LNP and mRNA in a candidate HIV vaccine, University of Pennsylvania

**2020**  
Development of mRNA-based SARS-CoV-2 vaccines by Pfizer/BioNTech and Moderna

**January 2020**  
Identification and public sharing of the genomic sequence of SARS-CoV-2 (including the sequence of the spike protein), from Fudan University
Box 3. What is an Observation, and How Does it Work? What is the Difference Between an Opposition and an Observation?

• **An observation:** Any person can file a so-called Third Party Observation (TPO) on a patent application that has been submitted at the EPO (according to Article 115 of the EPC). A TPO is a document that argues that a patent should not be granted. The EPO examiners may look at TPO during the examination process for patent applications if they want to, however, they have no obligation to do so - or to take the TPO into account. Observations have thus a very limited impact, and almost no statistics on TPO submissions are provided by EPO.

• **An opposition:** A patent opposition is an administrative proceeding which allows any person to challenge the validity of a patent with the office that granted it – and with a view to obtaining revocation of the patent. A patent opposition can be based on the grounds that one or more patentability criteria have not been met by the application. In the case of medicines, patent oppositions can permit the production of affordable generic versions by other manufacturers. They have been used on numerous occasions to defend access to affordably-priced medicines. Civil society have opposed patents in many countries (including Argentina, Brazil, India, Thailand, Ukraine, and the United States), to revoke unfair patents and enable production of more affordable generic versions of medicines. MdM has already filed several patent oppositions, including two covering Sovaldi® (claimed by Gilead Sciences), and one covering Kymriah®, a cancer treatment, (claimed by Novartis). One of the oppositions on the Sovaldi® patents has compelled Gilead Sciences to amend its patent, and helped draw attention to IP abuse, monopolies and pricing. After MdM filed its opposition on Kymriah at EPO, Novartis rapidly asked for dismissal of the patent.

Other examples of dodgy Covid-19 vaccine patents exist, including a patent from Moderna which basically follows the same principle as the BioNTech applications (applying existing technology on the sequence of the SARS-CoV-2 spike protein), which was filed in 2020, just 15 days after the genomic sequence of SARS-CoV-2 was made public.

Granting unmerited patents like these disrespects basic patentability criteria. By validating these dogdy patents, the EPO gives the illusion that they are legitimate. Since patents are property titles, granting them gives the impression that BioNTech, Pfizer and/or Moderna have a valid monopoly on the production and use of these vaccines. Granting these patents also contributes to creating risky situations for researchers and/or companies. An expert in the field can argue that the patents are dodgy, and that even if granted they should not prevent someone else from producing or using other mRNA-based Covid-19 vaccines. But with this property title in their hands, BioNTech/Pfizer and/or Moderna can always bring the matter to court, and they have more legal and financial means to do so than small producers or researchers, making it more difficult for others to risk developing their own product: they need the courage and the means to invest in it, and the expertise to see through dodgy patents to do so.

Thus, granting of patents contributes to creating a dominant position for Pfizer, BioNTech and Moderna.

**Doctor's of the World Opposes the Patent on SOFOSSBUVIR**

**HEPATITIS C: SCOURGE, REMEDY AND SCANDAL**
In some countries the “intellectual property” law provides the opportunity for third parties to file an opposition to a patent that has been requested at the patent office, before it has been granted. Pre-grant oppositions are compliant with the WTO Trade-Related Aspects of Intellectual Property Rights (TRIPS) standards, and they can prevent undue monopolies. Pre-grant oppositions are possible in Azerbaijan, Australia, Colombia, Costa Rica, Côte d’Ivoire, Ecuador, Egypt, Honduras, India, Israel, Mongolia, New Zealand, Pakistan, Peru, Portugal, Sri Lanka, Thailand, Zambia, Zimbabwe, and African Organization of Intellectual Property (AIP0) countries. However, according to the European Patent Convention (EPC), observations are the only mechanism for raising concerns about a patent before it is granted, and EPO examiners do not have to take the observation into account.

MDM’s Patent Observations Highlight Abuses and Imbalances in the “intellectual property” system, and how it is implemented.

MDM is using the only means available to question the two BioNTech patents. Beyond filing these observations, MDM is also raising issues about the patent granting process at the EPO level, and the quality of patents it has granted (see Box 4). The weakness and limitations of the observation process urgently call for individual European countries to amend their laws to introduce pre-grant opposition, and for the European Patent Convention to be revised to include this option. MDM also believes that the EPO should generally increase its requirements for the quality of patents it grants, and consider the social cost of granting undue monopolies for European populations and societies.


Box 4. Weak Criteria for, and Examination of Patents Leads to Multiplication of Monopolies

Patents are proliferating across the world. The number of patent applications, and granted patents, are steadily increasing overtime. This phenomenon does not reflect an increase in innovation - instead, it shows the weakening of standards for patent-granting.

The whole patent system, which is supposed to reward genuine inventions, is dysfunctional. Although national patent offices have some flexibility to implement strict standards, they rarely use it. Instead of being used for its original purpose, the patent system is keeping scientific advances and their benefits from the public - who often fund their discovery - and providing certain players with undeserved monopoly positions. In 2020, worldwide, the number of patents in force grew by 5.9%, reaching around 15.9 million. The US was home to the highest number of patents in force (3.3 million), followed by China (3.1 million), Japan (2 million) the Republic of Korea (1.1 million) and Germany (0.8 million). Patent proliferation is particularly high in the pharmaceutical sector, where large companies seek to control broad patent portfolios to extend patent protection beyond the expiry date of the original patents on new compounds. Low patentability standards allow "evergreening," the practice of multiplying patents on variations of the original product (such as slight modifications of the chemical structure that do not change its action, new controlled release versions of the drug, new dosages, new combinations or variations, etc). Dubious patents maintain monopolies, causing high prices for years beyond the 20 year-span of the original patent.

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3. THE STATE MUST RECONNECT WITH GENERAL INTEREST (AND STOP SERVING THE AGENDA OF THE MULTINATIONALS)

To ensure that global needs for Covid-19 vaccines were met, and to avoid allowing the few vaccine producers to have a monopoly on them, governments could have taken, and can still take, many actions. First, patent offices can avoid granting dodgy patents, including the two that MDM is contesting. Second, WTO Member States should grant a waiver on patent protection applying to Covid-19 medical technologies (see Box 5). Finally, France, as other states, can grant compulsory licenses (CL; see Box 6) to allow other producers to manufacture Covid-19 vaccines.

Box 5. Request for a Waiver at the WTO

In October 2020, South Africa and India introduced a request for a waiver on Covid-19 technologies (vaccines, medicines, diagnostics, etc.) at the WTO, which would allow countries to lift IP barriers on Covid-19 technologies. Although IP protection is not the only obstacle to an effective global fight against Covid-19, removing it is a necessary step to enable production and supply of these technologies to all who need them.

Several Western countries are blocking the process (especially, European countries). In March 2022, a purported compromise text was leaked. This text has many limitations and falls short of providing a solution for overcoming IP obstacles. It only covers vaccines, and it preserves IP rights such as the protection of know-how and marketing exclusivity - which are also barriers to widespread access. It would be applied on a product-by-product basis, and it excludes certain countries, including Brazil and China, which have the capacity to produce vaccines and other medical products.

Despite what multinational pharmaceutical companies have been saying since 2020, access to Covid-19 vaccines could be changed dramatically. Production of Covid-19 vaccine could be organized relatively easily on the earth’s five continents. Actually, it is technically easier and faster to produce mRNA-based vaccines than traditional protein-based vaccines, since mRNA vaccines are produced by biochemical reactions in test tubes that occur within hours). With the appropriate technology transfer, production of mRNA-based Covid-19 vaccines could be launched in many places very quickly. Even without technology transfer, local researchers or companies can use reverse
engineering to produce vaccines, although the process is time-consuming. South Africa’s Afrigen Biologics and Vaccines has developed its own mRNA-based Covid-19 vaccine, which is similar to Moderna’s vaccine. The capacity to produce mRNA-based vaccines exists in many countries across the world’s five continents.

Creating patent monopolies on Covid-19 vaccines has created an artificial shortage amid urgent calls to provide them to vulnerable populations and health professionals, although massive public resources were spent on vaccine R & D and production. mRNA vaccine research was made possible by decades of public support for basic research, including from the NIH, which allocated USD 17.2 billion between 2000 and 2019. Since 2019, an estimated USD 51.5 million in public and philanthropic funding has gone to development, production and supply of Covid-19 vaccines (see Figure 2).

While the theoretical justification for patents is to ensure that inventors are paid back for their investments in R & D, it is made obvious here that these monopoly rights serve accumulation of gigantic profits. In 2021, Pfizer, the most profitable pharmaceutical company, more than doubled its net income and reached almost USD 22 billion its net income.

The Covid-19 vaccine R & D well illustrates the fact that medical R & D is a collective effort. Public support generally takes many forms: funding by research agencies and national health institutions, public-private partnerships, tax rebates, in-kind contributions through from hospitals, research and health professionals work, and patients’ participation in clinical trials, etc. The fact that large multinationals generally end up controlling the right over the results of this collective effort is a problem. At least partial control by the public on the technology should exist, to allow a fairer share on the public investments.

This would also allow fairer negotiations on the supply and pricing of products. Abuses in pricing are regularly commented on in the media, for instance, in the case of cancers. And the price of treatments for so-called “rare” diseases continues to rise, often amounting to several hundred thousand euros per treatment and per patient, and sometimes exceeding a million euros, like with Zolgensma® that was priced_clomed on in the media, for instance, in the case of cancers. And the price of treatments for so-called “rare” diseases continues to rise, often amounting to several hundred thousand euros per treatment and per patient, and sometimes exceeding a million euros, like with Zolgensma® that was priced 1.5 million per patient by Novartis.

Box 6. The use of Compulsory Licenses

A compulsory license (CL) authorizes a third party to produce or use a patented product or process without the consent of the patent owner, based on an administrative or judicial decision. It is one of the flexibilities included in the WTO’s agreement on intellectual property – the TRIPS Agreement.

Several governments took steps to facilitate CL use during the pandemic, including Brazil, Bulgaria, Canada, Chile, Colombia, Ecuador, Germany, Hungary. In 2021, Brazil created a new two-step CL process allowing licenses to be granted for a list of essential products and the necessary manufacturing processes for them when a state of emergency has been declared. In Germany, an amendment to the German Act on the Prevention and Control of Infectious Diseases in Humans came into force in March 2020; it grants Parliament authority to determine the existence of an epidemic of national significance. On grounds of public interest or national security, the Federal Ministry for Health is authorized to order the responsible authority to allow the use of patent-protected inventions to ensure the supply of various health technologies, including medicines, diagnostics and personal protection equipment.

Several countries issued CL on products considered effective against Covid-19 (Israel on lopinavir/ritonavir; and Hungary and Russia on remdesivir, but there were no CL on vaccines).

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In the case of Covid-19 vaccines, agreeing to pay 20 euros per dose may seem acceptable, but, considering the public investment in R & D and the production (see Box 7 and Figure 6), and given that it only costs between 1 and 2.5 euros per dose to produce. Paying twice is problematic and strains national budgets (see Figure 5). When you multiply the number of doses by the dozens of millions of people in a country like France (80% of 66 million) you end up with a massive expense (see Box 8).

Such policies demonstrate a serious unbalance between health stakes and government arbitrations. They underscore how policy makers manage and use public resources, and the lack of transparency and democratic control over them.

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De son côté, AstraZeneca a fixé le prix de son vaccin à 1,73 euros par dose.

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Box 8. The Needs of Hospitals Vs the Resources Transferred to Pharmaceutical Multinationals

According to the “commission des comptes de la Sécurité sociale”, France spent 2.5 billion euro on Covid-19 vaccines in 2021. In 2021 the so-called “Sécur de la Santé”, the emergency national conference organized by the government in response to the massive mobilization and complaints from health professionals, raised 1.5 billion in 2021.

Hospital cost-cutting reached 1.050 million euro in 2019 and 900 million euro in 2020. Since 2020, more than 80,000 beds in public hospitals have been closed; their capacity has been reduced by 25% over the last 20 years.

MDM believes that such issues should urgently be debated as the social cost of these policies have an impact on other needs in the health system that are neglected and ultimately impact all of us.
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